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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,504	10/25/2001	Greg H. Lambrecht	INTRIN.001CP3	7447

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EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/22/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/055,504

Applicant(s)

LAMBRECHT ET AL.

Examin r

Thomas C. Barrett

Art Unit

3738

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 9.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-29, and 31-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (5,755,797) as cited in Applicant's IDS. Baumgartner discloses a disc augmentation device for replacement of part of a nucleus (col. 5, lines 49-53) to restore disc height and pressure comprising an annulus augmentation device (FIG. 4e) and a spherical nuclear augmentation device (7). The nuclear augmentation devices have a substantial portion of their surfaces not in contact with the annulus augmentation device. In a first embodiment (Fig. 1), most nuclear augmentation devices would have no contact at all with the annulus augmentation device of FIG. 4e.

In addition, the nuclear augmentation material will inherently cause the growth or formation of material within the nuclear space whether by an inflammatory response, response to the forces exerted by the augmentation material, scarring etc.

Both the annulus augmentation device and the nuclear augmentation material are **removable**, though they may not be intended to be.

The implant may comprise tantalum (col. 2, lines 48-52), which is capable of changing phase, though not at body temperature. The applicant may consider adding a limitation such as "capable of changing phase within an intervertebral disc space".

The nuclear augmentation device may comprise a polyurethane solid or a hydrogel (col. 2, lines 53-55). Please note that the solid polyurethane embodiment reads over claims 1-7, 9-14, 16-18, 21-29, 31-36 and 38-40 and the hydrogel embodiment reads over claims 1-7, 9, 11-12, 14-16, 19-29, 31, 33-34, 36-38, and 41-42. This is because the claims are written such that if one were to use, i.e. a solid for the nuclear augmentation material, it would not matter what the gels, liquids or gasses comprise. It is suggested that the applicant write a dependent claim for each material. For example:

43. (New) The system of Claim 9, wherein said nuclear augmentation material is a liquid.

The applicant would then amend the dependency of Claim 11 to Claim 43.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8, 23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (5,047,055) in view of Bao et al. (6,244,630). Bao et al. '055 discloses a nuclear augmentation device comprising a pharmacologically active agent (col. 6, lines 4-10) however '055 fails to disclose an annulus augmentation device. Bao et al. '630 teaches an annulus augmentation device (Fig. 3) to seal an opening in the anulus that has been initiated surgically and permit natural tissue ingrowth into the annular device (col. 2, lines 48-64). It would have been obvious to one of ordinary skill in the art to combine the teaching of an annulus augmentation device, as taught by Bao et al. '630, to a nuclear augmentation device as per Bao et al. '055, in order to seal an opening in the anulus that has been initiated surgically and permit natural tissue ingrowth into the annular device.

Please Note: The claims based on the new disclosure (claims 6-7, 10-11, 13-16, 18, 20, 28-29, 32-33, 35-38, 40 and 42) receive the filing date of the present application for determining priority. It has been noted that the Applicant has reserved the right to determine priority of said claims at a later date.

Furthermore, all suggested alterations above would require further search.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

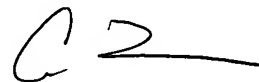
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3580 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0850.



Thomas Barrett
September 12, 2003



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700